

APPENDIX A

EXEMPLARY SUPPORT IN THE '779 APPLICATION⁵

Pending Claim Text	Exemplary Disclosure In The '779 Application
<p>54. A vaccine which protects a pig against a porcine reproductive and respiratory syndrome (PRRS), comprising;</p> <p>an effective amount of a biologically-pure virus selected from the group consisting of ISU-51 (VR 2429), ISU-55 (VR 2430), ISU-3927 (VR 2431), and ISU-1894 (VR 2475),</p> <p>wherein said virus is attenuated, and a physiologically-acceptable carrier,</p>	<p><u>Page 1, Lines 15-22:</u> "The present invention concerns . . . a vaccine which protects a pig from a PRRSV based on the protein or DNA, a method of protecting a pig from a PRRSV using the vaccine"</p> <p><u>Page 60, Lines 4-23:</u> "The present invention may also concern a biologically pure virus, characterized in that it contains the present polynucleic acid and/or that it causes a porcine reproductive and respiratory disease which may include one or more of the following histological lesions: gross and/or microscopic lung lesions (e.g., lung consolidation), Type II pneumocytes, myocarditis, encephalitis, alveolar exudate formation and syncytia formation. The phrase 'biologically pure' refers to a sample of a virus or infectious agent in which all progeny are derived from a single parent. Usually, a 'biologically pure' virus sample is achieved by 3 x plaque purification in cell culture. In particular, the present biologically pure virus or infectious agent is an isolate of the Iowa strain of porcine reproductive and respiratory syndrome virus, samples of which have been deposited . . . under the accession numbers VR 2385, VR 2386, VR 2428, VR 2429, VR 2430, VR 2431"</p> <p><u>Page 32, Lines 4-25:</u> ". . . The primary types of vaccines on which the present invention focuses include a subunit vaccine (Figure 1) and a genetically engineered vaccine (Figure 2). However,</p>

⁵ Applicants provide the following exemplary support for the pending claims and expressly reserve the right to amend and/or supplement the support listed.

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<p>wherein said virus is prepared by serial passage</p> <p>in a cell line selected from the group consisting of PSP-36, PSP-36-SAH, and MA-104.</p>	<p>other types of vaccines recognized in the field of veterinary vaccines, including live, modified live, attenuated and killed virus vaccines, are also acceptable. . . . An attenuated virus may be obtained by repeating serial passage of the virus in a suitable host cell a sufficient number of times to obtain an essentially non-virulent virus. . . ."</p> <p>Page 61, Lines 6-11: "The present invention further comprises a composition for protecting a pig from viral infection, comprising an amount of the present vaccine effective to raise an immunological response to a virus which causes a porcine reproductive and respiratory disease and a physiologically acceptable carrier."</p> <p>Page 32, Lines 4-25: ". . . The primary types of vaccines on which the present invention focuses include a subunit vaccine (Figure 1) and a genetically engineered vaccine (Figure 2). However, other types of vaccines recognized in the field of veterinary vaccines, including live, modified live, attenuated and killed virus vaccines, are also acceptable. . . . An attenuated virus may be obtained by repeating serial passage of the virus in a suitable host cell a sufficient number of times to obtain an essentially non-virulent virus. . . ."</p> <p>Page 36, Lines 8-14: "Genetically engineered vaccines (Figure 2) begin with a modification of the general procedure used for preparation of the other vaccines. After plaque-purification, the PRRS virus may be isolated from a suitable tissue homogenate by methods known in the art, preferably by conventional cell culture methods using PSP-36, ATCC CRL 11171 or macrophage cells as hosts."</p>

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	<p>Page 68, Lines 3-16: "Preferably, the present vaccine is prepared from a virus or infectious agent cultured in an appropriate cell line. The cell line is preferably PSP-36 or an equivalent cell line capable of being infected with the virus and cultured. An example of a cell line equivalent to PSP-36 is the cell line PSP-36-SAH . . . Another equivalent cell line is MA-104"</p> <p>Page 28, Line 22 to Page 29, Line 10: "The 'Iowa strain' of PRRSV refers to . . . (c) strains which, after no more than 5 passages, grow to a titer of at least 10⁴ TCID₅₀ in CRL 11171 cells, MA-104 cells or PSP-36 cells"</p>
<p>55. A vaccine which protects a pig against a porcine reproductive and respiratory syndrome (PRRS), comprising;</p> <p>an effective amount of a biologically-pure virus selected from the group consisting of ISU-51 (VR 2429), ISU-55 (VR 2430), ISU-3927 (VR 2431), and ISU-1894 (VR 2475), or a virus exhibiting the identifying characteristics of a virus in said group,</p>	<p>Page 1, Lines 15-22: "The present invention concerns . . . a vaccine which protects a pig from a PRRSV based on the protein or DNA, a method of protecting a pig from a PRRSV using the vaccine"</p> <p>Page 60, Lines 4-23: "The present invention may also concern a biologically pure virus, characterized in that it contains the present polynucleic acid and/or that it causes a porcine reproductive and respiratory disease which may include one or more of the following histological lesions: gross and/or microscopic lung lesions (e.g., lung consolidation), Type II pneumocytes, myocarditis, encephalitis, alveolar exudate formation and syncytia formation. The phrase 'biologically pure' refers to a sample of a virus or infectious agent in which all progeny are derived from a single parent. Usually, a 'biologically pure' virus sample is achieved by 3 x plaque purification in cell culture. In particular, the present biologically pure virus or infectious agent is an isolate of the Iowa strain of porcine reproductive and respiratory syndrome virus, samples of which have been deposited . . . under the accession</p>

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<p>wherein said virus is attenuated, and a physiologically-acceptable carrier,</p>	<p>numbers VR 2385, VR 2386, VR 2428, VR 2429, VR 2430, VR 2431”</p> <p>Page 248, Original Claim 15: “the vaccine of Claim 13, wherein said virus causes a disease characterized by one or more of the following symptoms and clinical signs: respiratory distress, fever and a reproductive condition in a sow selected from the group consisting of abortion, stillbirth, weak-born piglets, type II pneumocyte formation , myocarditis, encephalitis, alveolar exudate formation and syncytia formation.”</p>
<p>wherein said virus is prepared by serial passage</p>	<p>Page 32, Lines 4-25: “. . . The primary types of vaccines on which the present invention focuses include a subunit vaccine (Figure 1) and a genetically engineered vaccine (Figure 2). However, other types of vaccines recognized in the field of veterinary vaccines, including live, modified live, attenuated and killed virus vaccines, are also acceptable. . . . An attenuated virus may be obtained by repeating serial passage of the virus in a suitable host cell a sufficient number of times to obtain an essentially non-virulent virus. . . .”</p> <p>Page 61, Lines 6-11: “The present invention further comprises a composition for protecting a pig from viral infection, comprising an amount of the present vaccine effective to raise an immunological response to a virus which causes a porcine reproductive and respiratory disease and a physiologically acceptable carrier.”</p> <p>Page 32, Lines 4-25: “. . . The primary types of vaccines on which the present invention focuses include a subunit vaccine (Figure 1) and a genetically engineered vaccine (Figure 2). However, other types of vaccines recognized in the field of veterinary vaccines, including live</p>

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<p>in a cell line selected from the group consisting of PSP-36, PSP-36-SAH, and MA-104.</p>	<p>modified live, attenuated and killed virus vaccines, are also acceptable. . . . An attenuated virus may be obtained by repeating serial passage of the virus in a suitable host cell a sufficient number of times to obtain an essentially non-virulent virus. . . ."</p> <p>Page 36, Lines 8-14: "Genetically engineered vaccines (Figure 2) begin with a modification of the general procedure used for preparation of the other vaccines. After plaque-purification, the PRRS virus may be isolated from a suitable tissue homogenate by methods known in the art, preferably by conventional cell culture methods using PSP-36, ATCC CRL 11171 or macrophage cells as hosts."</p> <p>Page 68, Lines 3-16: "Preferably, the present vaccine is prepared from a virus or infectious agent cultured in an appropriate cell line. The cell line is preferably PSP-36 or an equivalent cell line capable of being infected with the virus and cultured. An example of a cell line equivalent to PSP-36 is the cell line PSP-36-SAH . . . Another equivalent cell line is MA-104"</p> <p>Page 28, Line 22 to Page 29, Line 10: "The 'Iowa strain' of PRRSV refers to . . . (c) strains which, after no more than 5 passages, grow to a titer of at least 10⁴ TCID₅₀ in CRL 11171 cells, MA-104 cells or PSP-36 cells"</p>
<p>56. A vaccine which protects a pig against porcine reproductive and respiratory syndrome (PRRS), comprising</p> <p>an inactivated or attenuated virus wherein prior to inactivation or attenuation,</p>	<p>Page 1, Lines 15-22: "The present invention concerns . . . a vaccine which protects a pig from a PRRSV based on the protein or DNA, a method of protecting a pig from a PRRSV using the vaccine"</p> <p>Page 32, Lines 4-25: ". . . The primary types of vaccines on which the present invention focuses include a subunit vaccine (Figure 1) and a genetically</p>

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<p>said virus is selected from the group consisting of ISU-51 (VR 2429), ISU-55 (VR 2430), ISU-3927 (VR 2431), and ISU-1894 (VR 2475), and</p> <p>a physiologically-acceptable carrier,</p>	<p>engineered vaccine (Figure 2). However, other types of vaccines recognized in the field of veterinary vaccines, including live, modified live, attenuated and killed virus vaccines, are also acceptable. . . . An attenuated virus may be obtained by repeating serial passage of the virus in a suitable host cell a sufficient number of times to obtain an essentially non-virulent virus. . . ."</p> <p>Page 60, Lines 4-23: "The present invention may also concern a biologically pure virus, characterized in that it contains the present polynucleic acid and/or that it causes a porcine reproductive and respiratory disease which may include one or more of the following histological lesions: gross and/or microscopic lung lesions (e.g., lung consolidation), Type II pneumocytes, myocarditis, encephalitis, alveolar exudate formation and syncytia formation. The phrase 'biologically pure' refers to a sample of a virus or infectious agent in which all progeny are derived from a single parent. Usually, a 'biologically pure' virus sample is achieved by 3 x plaque purification in cell culture. In particular, the present biologically pure virus or infectious agent is an isolate of the Iowa strain of porcine reproductive and respiratory syndrome virus, samples of which have been deposited . . . under the accession numbers VR 2385, VR 2386, VR 2428, VR 2429, VR 2430, VR 2431"</p> <p>Page 61, Lines 6-11: "The present invention further comprises a composition for protecting a pig from viral infection, comprising an amount of the present vaccine effective to raise an immunological response to a virus which causes a porcine reproductive and respiratory disease and a physiologically acceptable carrier."</p>

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<p>wherein said inactivated or attenuated virus is prepared by serial passage</p>	<p>Page 32, Lines 4-25: "... The primary types of vaccines on which the present invention focuses include a subunit vaccine (Figure 1) and a genetically engineered vaccine (Figure 2). However, other types of vaccines recognized in the field of veterinary vaccines, including live, modified live, attenuated and killed virus vaccines, are also acceptable. ... An attenuated virus may be obtained by repeating serial passage of the virus in a suitable host cell a sufficient number of times to obtain an essentially non-virulent virus. ..."</p>
<p>in a cell line selected from the group consisting of PSP-36, PSP-36-SAH, and MA-104.</p>	<p>Page 36, Lines 8-14: "Genetically engineered vaccines (Figure 2) begin with a modification of the general procedure used for preparation of the other vaccines. After plaque-purification, the PRRS virus may be isolated from a suitable tissue homogenate by methods known in the art, preferably by conventional cell culture methods using PSP-36, ATCC CRL 11171 or macrophage cells as hosts."</p>
	<p>Page 68, Lines 3-16: "Preferably, the present vaccine is prepared from a virus or infectious agent cultured in an appropriate cell line. The cell line is preferably PSP-36 or an equivalent cell line capable of being infected with the virus and cultured. An example of a cell line equivalent to PSP-36 is the cell line PSP-36-SAH ... Another equivalent cell line is MA-104 ..."</p>
	<p>Page 28, Line 22 to Page 29, Line 10: "The 'Iowa strain' of PRRSV refers to ... (c) strains which, after no more than 5 passages, grow to a titer of at least 10^4 TCID₅₀ in CRL 11171 cells, MA-104 cells or PSP-36 cells ..."</p>